

1 We Claim:

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5 1. An electrotransport device for in vivo delivery of a charged agent
6 through a body surface at a higher electrotransport agent delivery efficiency (E)
7 defined by the agent delivery rate per unit of applied current; the device (10) having
8 a donor reservoir (26, 46) containing the charged agent and having a delivery area,
9 and having a source of electrical power (32) and a current controller (19, 40), the
10 device (10) being characterized by:

11 the current controller (19, 40) being adapted to provide an applied pulsing
12 current having a periodic current waveform, a pulsing frequency, and a duty cycle,
13 the pulsing current applied to the reservoir (26, 46) and to the body surface, wherein
14 an applied current density is defined by the applied pulsing current divided by the
15 delivery area, and wherein the body surface exhibits a higher electrotransport agent
16 delivery efficiency (E) when the applied current density is greater than or equal to a
17 critical current density level (I_c) and the applied pulsing current is applied for greater
18 than or equal to a critical time period (t_c).
19

20 2. The device of claim 1, wherein the agent delivery efficiency (E) is more
21 stable when the applied current density is above the critical level (I_c) and less stable
22 when the applied current density is below the critical level (I_c).
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24 3. The device of claim 1, wherein the device (10) is adapted to be applied
25 to intact human skin and the controller (19, 40) is adapted to provide an applied
26 current density of at least about $40 \mu\text{A}/\text{cm}^2$.
27

28 4. The device of claim 1, wherein the agent is fentanyl and the controller
29 (19, 40) is adapted to provide an applied current density of at least about $40 \mu\text{A}/\text{cm}^2$
for at least about 10 msec.

1 5. The device of claim 1, wherein the agent is goserelin and the controller
2 (19, 40) is adapted to vary and control the periodic current waveform to provide an
3 applied current density of at least about $50 \mu\text{A}/\text{cm}^2$ for at least about 10 msec.
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5 6. The device of claim 1, wherein t_c is at least 5 msec.
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7 7. The device of claim 1, wherein the periodic current waveform has a
8 current magnitude that provides a second applied current density less than I_c .
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10 8. The device of claim 7, wherein the second applied current density is
11 approximately zero.
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13 9. The device of claim 7, wherein the controller (19, 40) is adapted to
14 vary the duty cycle and the agent delivery rate.
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16 10. The device of claim 7, wherein the controller (19, 40) is adapted to
17 vary the frequency and the agent delivery rate.
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19 11. The device of claim 1, wherein the donor reservoir contains at least
20 one suitable competitive specie.
21

22 12. The device of claim 1, wherein the controller (19, 40) is adapted to
23 vary and control the frequency of the applied pulsing current to less than about 100
24 Hz.
25

26 13. The device of claim 1, wherein the controller (19, 40) is adapted to
27 vary and control the frequency of the applied pulsing current to less than about 10
28 Hz.

14. A method of in vivo delivery of a charged agent from an electrotransport delivery device (10) through a body surface at higher electrotransport agent delivery efficiency (E) defined by the agent delivery rate per unit of applied current; the device (10) having a donor reservoir (26, 46) containing the agent and having a delivery area, and having a source of electrical power (32) and a current controller (19, 40), the method being characterized by the steps of:

adapting the current controller (19, 40) to provide an applied pulsing current having a periodic current waveform, a pulsing frequency, and a duty cycle, the pulsing current applied to the reservoir (26, 46) and to the body surface, wherein an applied current density is defined by the applied pulsing current divided by the delivery area, and wherein the body surface exhibits a higher electrotransport agent delivery efficiency (E) when the applied current density is greater than or equal to a critical current density level (I_c) and the applied pulsing current is applied for greater than or equal to a critical time period (t_c).

15. The method of claim 14, wherein the agent delivery efficiency (E) is more stable at a current density above the critical level (I_c) and less stable at a current density below the critical level (I_c).

16. The method of claim 14, wherein the device is adapted to be applied to human skin, and the controller (19, 40) provides an applied current density at least about $40 \mu\text{A}/\text{cm}^2$.

17. The method of claim 14, wherein the agent is fentanyl, and the controller (19, 40) provides an applied current density of at least $40 \mu\text{A}/\text{cm}^2$ for at least about 10 msec.

18. The method of claim 14, wherein the pulsing frequency is less than about 100 Hz.

AMENDED SHEET

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1 19. The method of claim 14, wherein the pulsing frequency less than about
2 10 Hz.

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4 20. The method of claim 14, wherein the duty cycle is less than about
5 100%.

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7 21. The method of claim 14, wherein the body surface comprises intact
8 human skin and I_c is at least about $40 \mu A/cm^2$.

9
10 22. The method of claim 14, wherein the agent is fentanyl, the body
11 surface is intact human skin, and the applied pulsing current is equal to I_c which is at
12 least about $40 \mu A/cm^2$, and wherein the pulsing current is applied for at least about
13 10 msec.

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15 23. The method of claim 14, wherein the agent is goserelin, and the
16 applied pulsing current is at least about $50 \mu A/cm^2$, and wherein the pulsing current
17 is applied for at least about 10 msec.

18
19 24. The method of claim 14 further including the step of varying the duty
20 cycle and the agent delivery rate.

21
22 25. The method of claim 14 further including the step of varying the
23 pulsing frequency and the agent delivery rate.

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25 26. The method of claim 14 further including the step of adding a suitable
26 competitive specie to the donor reservoir (26, 46).